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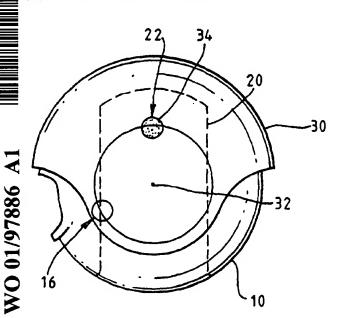
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(54) Title: MEDICAMENT DISPENSER



(57) Abstract: There is provided a medicament dispenser for dispensing medicament comprising a body (10) having a dispensing outlet (12); within said body, a medicament container (20) for containing medicament; a dose mover (34) reversibly movable from an initial position to a dispensing position in which the medicament is presented a the dispensing outlet (12); and a dispensing outlet cover (30), movable relative to the body (10) from a storage position in which the dispensing outlet is covered to and in-use position in which the dispensing outlet is exposed, wherein the movement of the outlet cover (30) from the storage position to the in-use position is coupled to the movement of the a dose mover (34) from the initial position to the dispensing position.

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### Medicament dispenser

The present invention relates to a medicament dispenser for use in the administration of medicament in powder form to a patient.

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The use of inhaler devices in the administration of medicaments, for example in bronchodilation therapy, is well known. Such devices generally comprise a body or housing within which a medicament container is located. Known inhaler devices include those in which the medicament container is suitable for containing a bulk reservoir of dry powder medicament. Such devices also typically comprise a mechanism for metering a dose from the reservoir and for transferring the dose to a delivery position where it is available for inhalation by the patient. These devices tend to be relatively size efficient in that they enable a large number of doses to be contained within a relatively device volume.

WO96/08284 and WO98/30262 describe representative reservoir based dry powder medicament dispensers in which powder doses are metered from a reservoir to a delivery position in which the dose is inhalable by the patient. PCT Patent Application No. WO00/35522 describes a reservoir based dry powder medicament dispenser in which the metering system employs a rotatable auger to transfer powder from the reservoir to the delivery position.

A mouthpiece (or nozzle) is typically provided to the inhaler device, wherein 'in use' the mouthpiece communicates with the powder delivery position to allow passage of the metered medicament dose to the mouthpiece and thence, to the patient. In a typical dispensing operation the body of the device is held by the patient and the mouthpiece (or nozzle) of the inhaler device is placed in the mouth (or nose) of the patient. The patient inhales, thereby causing transfer of

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the medicament dose from the delivery position to the interior of the body of the patient.

When not in use it is desirable, from a hygiene standpoint that the mouthpiece is provided with some kind of protective cover. The cover desirably acts both to prevent build-up of dirt on the mouthpiece and to prevent ingress of dirt into the body of the device through the mouthpiece, which might then be subject to inhalation by a patient. It is desirable, from a hygiene standpoint, that the mouthpiece does not come into contact with the hands of the user during the mouthpiece uncovering process.

Various sorts of mouthpiece cover have been proposed including detachable caps and lids. It is however, desirable that the cover is in some way attached or mounted to the device to minimise the risk that the cover is misplaced or lost.

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US-A-6,032,666 describes a medicament dispenser having a mouthpiece cover which is rotationally mounted to the body of the device and rotatable from a first position in which the mouthpiece is covered thereby to a second position in which the mouthpiece is exposed.

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It is desirable that the operation of a medicament dispenser be straightforward and non-complex and in particular, that the number of separate steps involved in preparing the device for use be minimised. This is especially relevant where the device is designed for use in the delivery of medicament in emergency or rescue situations (e.g. asthma attacks) where simplicity and ease of use is paramount.

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The Applicants have therefore now devised a medicament dispenser having a dispensing outlet cover in which the actions of the transfer of a dose from to a delivery position and the opening of the dispensing outlet cover to reveal the

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dispensing outlet are operable in tandem. The device is therefore simple and straightforward to 'prime' for use by a patient.

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According to one aspect of the present invention there is provided a medicament dispenser for dispensing medicament comprising a body having a dispensing outlet; within said body, a medicament container for containing medicament; a dose mover reversibly movable from an initial position to a dispensing position in which the medicament is presented at the dispensing outlet; and a dispensing outlet cover, movable relative to the body from a storage position in which the dispensing outlet is covered to an in-use position in which the dispensing outlet is exposed, wherein the movement of the outlet cover from the storage position to the in-use position is coupled to the movement of the a dose mover from the initial position to the dispensing position.

In one aspect, the medicament container is in the form of a reservoir container suitable for containing a reservoir of medicament, and said dose mover comprises a dose meter reversibly movable from an initial position wherein said dose meter communicates with the medicament container to receive a metered amount (e.g. volume or weight) of medicament therefrom to a dispensing position in which the dose meter communicates with the dispensing outlet.

Preferably, the dose meter comprises a metering recess therein. The metering recess may have any suitable shape such as an indent, a hemispherical cup, an elongate passage or a groove. It may meter a single dose of medicament or defined fraction or multiple thereof. Technical equivalents to the metering recess are envisaged including rod or shaft arrangements.

The medicament container may be provided with means to urge powder in the reservoir to a reservoir outlet that communicates in the initial position with the

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metering recess. The urging means may comprise various means of providing suitable biasing force such as spring loading means or vacuum means.

Suitably, one or more seals are provided between the dose meter and the medicament container. In one aspect, the seal comprises hard, incompressible mating surfaces which may be polished. In another aspect, the seal comprises a first mating surface formed from a hard, incompressible material and a second mating surface formed from a softer, more compressible material.

The seals may be formed by any suitable process including moulding processes such as one or two-shot moulding processes.

The seals may be comprised of any suitable sealing materials including organic polymeric materials, metals, resins or ceramics.

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In another aspect, the medicament container is in the form of a medicament carrier suitable for carrying one or more discrete medicament doses, and the a dose mover comprises a mechanism for presenting at least one discrete medicament dose to a dispensing position in which the at least one discrete medicament dose communicates with the dispensing outlet.

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Suitably, the carrier is in the form of a blister pack or pack having discrete doses of medicament printed or otherwise adhered thereto. Carriers for carrying a unit dose medicament are envisaged, as are those containing multiple unit doses arranged sequentially or otherwise, such as in series or matrix form. A particular multi-unit dose arrangement comprises an elongate strip having multiple unit doses of medicament arranged in series thereon (e.g. elongate blister strip).

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The dose mover preferably incorporates or is coupled to a dose liberator for liberating the at least one medicament dose from the carrier. Where the at least

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one discrete medicament dose is comprised within a sealed pack (e.g. a blister pack) the dose liberator may for example, comprise a means for opening the pack by e.g. a rupture, piercing or separating action.

Once presented at the dispensing position, the at least one medicament dose may be protected by a local dose protector e.g. to prevent contamination thereof before delivery to the patient. The local dose protector may in one example, comprise a flap which covers the dose (thereby providing some protection thereto) during the time after presentation but before delivery to the patient. In another aspect, the dose protector comprises a mesh or cruciform shield to prevent access (e.g. finger access) to the presented dose.

Once the dose mover has been actuated and the dose moved to the dispensing position it desirable to be able to prevent movement of the dose back into the dispenser (e.g. feeding it back into a reservoir). The dose mover may therefore be provided with a mechanism (e.g. ratchet) which prevents such reverse movement until such a point as the dose has been delivered. Alternatively, the dose mover may be provided with a mechanism such that the dose mover is subject to an emptying action (e.g. transfer of remaining dose into a waste chamber) during the course of the reverse movement.

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The movement of the dose mover and outlet cover may be arranged to be axial (i.e. in a straight line), arcuate, rotational or more complex. Preferably, the movement of the dose mover and outlet cover is of the same general type, that is to say e.g. both move axially, or in an arcuate sense or rotationally. More preferably, the movement is co-axial or co-arcuate or co-rotational sharing a common rotational axis.

In one aspect, the movement of the dose mover and outlet cover is coupled by a coupling mechanism. The coupling mechanism may comprise any suitable

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mechanism such as a gear mechanism, rack and pinion mechanism or hinged lever mechanism.

In another aspect, the movement of the dose mover and outlet cover is not directly coupled. Suitably, the dose mover and outlet cover share a common locus of movement, such a single axial track, a common pivot point or a common rotational axis.

The medicament container may be defined by the body. Alternatively, the medicament container is defined by an insert part. The insert may in one aspect comprise a cartridge which is reversibly locatable within the body. The body is typically arranged such that the cartridge is shaped for unique engagement therewith. Mechanical or electronic systems may be provided to enable recognition of the cartridge type including details of e.g. medicament type and recommended dose.

Suitably, the dose mover and/or outlet cover are provided with a safety trigger mechanism to prevent accidental movement thereof and/or false actuation. The mechanism may for example comprise a switch or latching mechanism.

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Suitably, at least a portion of the outlet cover is shaped for ease of grip by the user.

Suitably, at least a portion of the outlet cover has a friction-enhancing coating for ease of grip by the user.

Suitably, the dispenser is provided with a mechanical or electronic dose counter, which indicates the number of doses dispensed from or remaining in the container. Preferably, the dose counter comprises an indexing mechanism

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actuated by movement of the dose mover and/or outlet cover relative to the body.

Suitably the outlet cover is actuable by a thumb motion. Preferably, the outlet cover is actuable by one-handed operation such as one in which the body is gripped within the cupped fingers of a user and the cover is moved by a thumb action. Alternatively, non-manual (e.g. electromechanical) mechanisms for opening the cover are envisaged.

The body, medicament container, seals or any other part of the device may comprise a desiccant material. The desiccant material may be applied as a coating to any surface or be impregnated within any part of the device or it may be contained within a suitable enclosure within the device. Suitable desiccants are selected from organic polymeric plastics, polyamides (e.g. nylon), silica gel, zeolites, alumina, bauxite, anhydrous calcium sulphate, activated bentonite clay, water-absorbing clay, molecular sieves and any mixtures thereof.

Various electronic systems may be provided to the device including systems for monitoring actuation thereof; for counting the number of doses delivered or remaining; for checking compliance with a defined dose regime; for monitoring breath characteristics including peak flow; and for enabling unique recognition of a user such as by password protection. The electronic systems typically include some form of means for uploading data to the device from another computer system or downloading data from the device to another computer system.

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According to a further aspect of the present invention there is provided a reloadable medicament dispenser for dispensing medicament comprising a body having a dispensing outlet; within said body, a loading position for reversible receipt of a cartridge comprising a medicament container for containing medicament; a dose mover reversibly movable from an initial position to a

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dispensing position in which the medicament is presented at the dispensing outlet; and a dispensing outlet cover, movable relative to the body from a storage position in which the dispensing outlet is covered to an in-use position in which the dispensing outlet is exposed, wherein the movement of the outlet cover from the storage position to the in-use position is coupled to the movement of the dose mover from the initial position to the dispensing position.

There is also provided a cartridge comprising a medicament container reversibly receivable by the reloadable medicament dispenser described above. The medicament container may be in reservoir form or in carrier form and the dose mover may have any of the forms as described hereinbefore. Typically, the cartridge will be reversibly retained within the medicament dispenser by some sort of latching or locking mechanism.

The reloadable medicament dispenser and cartridge therefor may be supplied separately or may be supplied as a kit of parts.

The cartridge itself is typically supplied charged with medicament. It may be arranged to be reloadable with medicament.

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The medicament dispenser herein may be in the form of an inhaler device. Suitably, the dispensing outlet thereof defines a mouthpiece.

Herein the term 'mouthpiece' is used in a generic sense to mean an element shaped such as to be insertable into the mouth or nose of a patient for inhalation therethrough.

Suitably, the medicament dispenser herein comprises medicament. The medicament may in any suitable forms such as dry powder (either with excipient

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or excipient-free), liquid, solution, gaseous, suspension, tablet, capsule or nebule form. Preferably, the medicament is in dry powder form.

According to another aspect of the present invention, there is provided the use of a medicament dispenser provided herein for dispensing medicament.

Preferred embodiments of the medicament dispenser according to the present invention will now be described with reference to the accompanying drawings in which:

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Fig. 1a is a schematic side view of a first inhalation device in accord with the present invention, wherein the mouthpiece is in the storage position;

Fig. 1b is a schematic side view of the device of Fig. 1a, wherein the mouthpiece is in the in-use position;

Fig. 2a is a sectional side view of a first medicament dispenser in accord with the present invention, wherein the mouthpiece is in the storage position; and

Fig. 2b is a sectional side view of the device of Fig. 2a, wherein the mouthpiece is in the in-use position.

Figs. 1a and 1b show a first medicament dispenser herein in the open and closed positions. The device comprises a generally circular body 10 having an outlet 12 defining a mouthpiece 14. The body 10 is also provided with a dispensing orifice 16 which in the open position communicates with the outlet 12 and mouthpiece 14 for dispensing of medicament therethrough. Defined by the body 10 there is a medicament container 20 for containment of dry powder medicament. The container is provided with a delivery orifice 22 for delivery of powder. A cover 30 is provided to the body wherein the cover is pivotally

mounted 32 to the body 10 such that it is rotatable by 180° around the body 10. The inner part of the cover 30 is provided with a metering recess 34. In the cover closed position, the metering recess 34 is located adjacent the delivery orifice 22 of the medicament container 20 such that powder may enter the metering recess 34 therefrom. In the open position, the metering recess 34 locates adjacent the dispensing orifice 16 such that powder may pass therethrough to the outlet 12 and mouthpiece 14.

It may be appreciated that the device is operable by a single-handed operation in which the cover 30 is held in the cupped fingers (not shown) of a user and the body 10 rotated through 180° by a thumb action of the user to bring the device from the open to closed position and vice versa. It may also be appreciated that the 180° rotation of the cover 30 acts such as to either expose or cover the mouthpiece 14 and move the metering recess 34 from a loading position to a dispensing position.

Figs. 2a and 2b show a second medicament dispenser herein in the open and closed positions. The device comprises a generally circular body 110 having an outlet 112 defining a mouthpiece 114. The body 110 is also provided with a dispensing orifice 116 which in the open position communicates with the outlet 112 and mouthpiece 114 for dispensing of medicament therethrough. Within the body 110 there is a collapsible tube container 120 for containment of dry powder medicament. The container 120 is provided with a delivery orifice 122 for delivery of powder. A cover (not visible) is provided to the body wherein the cover is pivotally mounted such that it is rotatable by 180° around the body 110. The cover is co-axially mounted and rotationally coupled to drive wheel 140 such that rotation of the cover results in rotation of the drive wheel 140. The drive wheel engages metering wheel 150 which is provided with a metering recess 152. In the cover-closed position, the metering recess 52 is located adjacent the delivery orifice 122 of the medicament cartridge 120 such that powder may enter

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the metering recess 152 therefrom. In the open position, the metering recess 152 locates adjacent the dispensing orifice 116 such that powder may pass therethrough to the outlet 112 and mouthpiece 114.

It may be seen that the container 120 is also provided with a system for ensuring constant delivery of powder to the delivery orifice 122. The system comprises a collar 160 movable along a track 162 located on either side of the tubular container 120. Pull is applied to the collar 160 by constant force spring 164. As the collar 160 is pulled along the track 162 by the action of the spring 164 the tube 120 is squeezed and powder is urged towards the delivery orifice 122.

It may be appreciated that the device is operable by a single-handed operation in which the cover (not shown) is held in the cupped fingers (not shown) of a user and the body 110 rotated through 180° by a thumb action of the user to bring the device from the open to closed position and vice versa. It may also be appreciated that the 180° rotation of the cover acts such as to both expose or cover the mouthpiece 114 and move the metering recess 152 from a loading position to a dispensing position.

The medicament dispenser herein is suitable for dispensing medicament, particularly for the treatment of respiratory disorders.

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Appropriate medicaments may thus be selected from, for example, analgesics, e.g., codeine, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem; antiallergics, e.g., cromoglycate (eg s the sodium salt), ketotifen or nedocromil (eg as the sodium salt); antiinfectives e.g., cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines and pentamidine; antihistamines, e.g., methapyrilene; anti- inflammatories, e.g., beclomethasone (eg as the dipropionate ester), fluticasone (eg as the propionate ester), flunisolide, budesonide, rofleponide, mometasone eg as the furoate

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ester), ciclesonide, triamcinolone (eg as the acetonide) or  $6\alpha$ ,  $9\alpha$ -difluoro-11 $\beta$ hydroxy- $16\alpha$ -methyl-3-oxo- $17\alpha$ -propionyloxy-androsta-1,4-diene- $17\beta$ -carbothioic acid S-(2-oxo-tetrahydro-furan-3-yl) ester; antitussives, e.g., noscapine; bronchodilators, e.g., albuterol (eg as free base or sulphate), salmeterol (eg as xinafoate), ephedrine, adrenaline, fenoterol (eg as hydrobromide), formoterol (eg as fumarate), isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol (eg as acetate), reproterol (eg as hydrochloride), rimiterol, terbutaline (eg as sulphate), isoetharine, tulobuterol or 4-hydroxy-7-[2-[[2-[[3-(2-phenylethoxy)propyl]sulfonyl]ethyl]amino]ethyl-2(3H)benzothiazolone; adenosine 2a agonists, eg 2R,3R,4S,5R)-2-[6-Amino-2-(1Shydroxymethyl-2-phenyl-ethylamino)-purin-9-yl]-5-(2-ethyl-2H-tetrazol-5-yl)tetrahydro-furan-3,4-diol (e.g. as maleate); α₄ integrin inhibitors eg (2S)-3-[4-({[4-(aminocarbonyl)-1-piperidinyl]carbonyl]oxy)phenyl]-2-[((2S)-4-methyl-2-[[2-(2methylphenoxy) acetyl]amino}pentanoyl)amino] propanoic acid (e.g as free acid or potassium salt), diuretics, e.g., amiloride; anticholinergics, e.g., ipratropium (eg as bromide), tiotropium, atropine or oxitropium; hormones, e.g., cortisone, hydrocortisone or prednisolone; xanthines, e.g., aminophylline, choline theophyllinate, lysine theophyllinate or theophylline; therapeutic proteins and peptides, e.g., insulin or glucagon; vaccines, diagnostics, and gene therapies. It will be clear to a person skilled in the art that, where appropriate, the medicaments may be used in the form of salts, (e.g., as alkali metal or amine salts or as acid addition salts) or as esters (e.g., lower alkyl esters) or as solvates (e.g., hydrates) to optimise the activity and/or stability of the medicament.

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Preferred medicaments are selected from albuterol, salmeterol, fluticasone propionate and beclomethasone dipropionate and salts or solvates thereof, e.g., the sulphate of albuterol and the xinafoate of salmeterol.

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Medicaments can also be delivered in combinations. Preferred formulations containing combinations of active ingredients contain salbutamol (e.g., as the free base or the sulphate salt) or salmeterol (e.g., as the xinafoate salt) or formoterol (eg as the fumarate salt) in combination with an anti-inflammatory steroid such as a beclomethasone ester (e.g., the dipropionate) or a fluticasone ester (e.g., the propionate) or budesonide. A particularly preferred combination is a combination of fluticasone propionate and salmeterol, or a salt thereof (particularly the xinafoate salt). A further combination of particular interest is budesonide and formoterol (e.g. as the fumarate salt).

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It may be appreciated that any of the parts of the medicament container used therewith which contact the medicament may be coated with materials such as fluoropolymer materials which reduce the tendency of medicament to adhere thereto. Suitable fluoropolymers include polytetrafluoroethylene (PTFE) and fluoroethylene propylene (FEP). Any movable parts may also have coatings applied thereto which enhance their desired movement characteristics. Frictional coatings may therefore be applied to enhance frictional contact and lubricants used to reduce frictional contact as necessary.

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It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations and improvements thereto.

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The application of which this description and claims form part may be used as a basis for priority in respect of any subsequent application. The claims of such subsequent application may be directed to any feature or combination of features described therein. They may take the form of product, method or use claims and may include, by way of example and without limitation, one or more of the following claims:

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### **CLAIMS**:

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1. A medicament dispenser for dispensing medicament comprising

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within said body, a medicament container for containing medicament;

a dose mover reversibly movable from an initial position to a dispensing position in which the medicament is presented at the dispensing outlet; and

a dispensing outlet cover, movable relative to the body from a storage position in which the dispensing outlet is covered to an in-use position in which the dispensing outlet is exposed,

wherein the movement of the outlet cover from the storage position to the in-use position is coupled to the movement of the dose mover from the initial position to the dispensing position.

- 2. A medicament dispenser according to claim 1, wherein said medicament container is suitable for containing a reservoir of medicament, and said dose mover comprises a dose meter reversibly movable from an initial position wherein said dose meter communicates with the medicament container to receive a metered amount of medicament therefrom to a dispensing position in which the dose meter communicates with the dispensing outlet.
  - 3. A medicament dispenser according to claim 2, wherein the dose meter comprises a metering recess having a form selected from the group consisting of an indent, a hemispherical cup, an elongate passage and a groove.

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4. A medicament dispenser according to either of claims 2 or 3, additionally comprising urging means to urge medicament in the reservoir to a reservoir outlet of the medicament container that communicates in the initial position with the dose meter.

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- 5. A medicament dispenser according any of claims 2 to 4, wherein one or more seals are provided between the dose meter and the medicament container.
- 10 6. A medicament dispenser according to claim 1, wherein said medicament container is a medicament carrier suitable for carrying one or more discrete medicament doses, and the dose mover comprises a mechanism for presenting at least one discrete medicament dose to a dispensing position in which the at least one discrete medicament dose communicates with the dispensing outlet.
  - 7. A medicament dispenser according to claim 6, wherein the carrier is in the form of a blister pack.
- 20 8. A medicament dispenser according to either of claims 6 or 7, wherein the carrier is in the form of an elongate strip.
  - 9. A medicament dispenser according to any of claims 6 to 8, wherein the dose mover incorporates or is coupled to a dose liberator for liberating the at least one medicament dose from the carrier.
  - 10. A medicament dispenser according to any of claims 6 to 9, additionally comprising a dose protector to protect the at least one medicament dose at the dispensing position.

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- 11. A medicament dispenser according to any of claims 1 to 10, additionally comprising a mechanism to prevent reverse movement of the dose mover prior to delivery of the dose.
- 5 12. A medicament dispenser according to any of claims 1 to 11, additionally comprising a mechanism to empty the dose mover during reverse movement thereof.
- 13. A medicament dispenser according to any of claims 1 to 12, wherein the dose mover and the outlet cover are movable in a common fashion.
  - 14. A medicament dispenser according to any of claims 1 to 13, wherein the medicament container is defined by the body.
- 15. A medicament dispenser according to any of claims 1 to 13, wherein the medicament container is defined by an insert part.
  - 16. A medicament dispenser according to claim 15, wherein the insert comprises a cartridge which is reversibly locatable within the body.

- 17. A medicament dispenser according to any of claims 1 to 16, wherein the dose mover and/or outlet cover are provided with a safety trigger mechanism to prevent accidental movement thereof.
- 25 18. A medicament dispenser according to any of claims 1 to 17, additionally comprising a mechanical or electronic dose counter.
  - 19. A medicament dispenser according to any of claims 1 to 18, wherein the outlet cover is manually movable.

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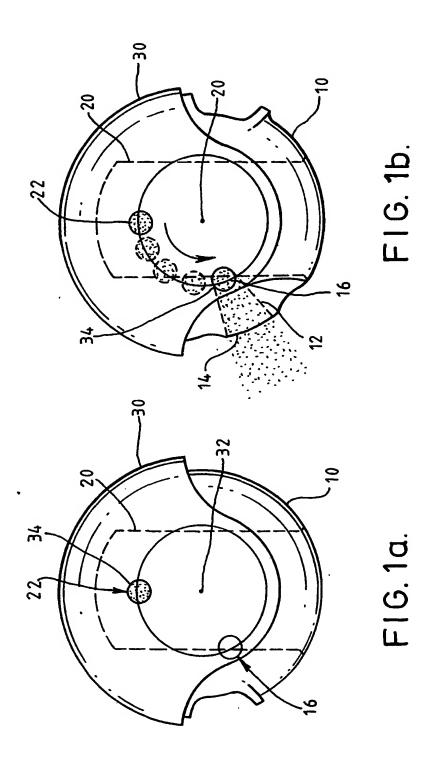
- 20. A medicament dispenser according to any of claims 1 to 19, additionally comprising a desiccant material located therein.
- 21. A medicament dispenser according to any of claims 1 to 20 in the form of an inhaler device, wherein the dispensing outlet defines a mouthpiece.
  - 22. A reloadable medicament dispenser for dispensing medicament comprising
- 10 a body having a dispensing outlet;
  - within said body, a loading position for reversible receipt of a cartridge comprising a medicament container for containing medicament;
- a dose mover reversibly movable from an initial position to a dispensing position in which the medicament is presented at the dispensing outlet; and
  - a dispensing outlet cover, movable relative to the body from a storage position in which the dispensing outlet is covered to an in-use position in which the dispensing outlet is exposed, wherein the movement of the outlet cover from the storage position to the in-use position is coupled to the movement of the dose mover from the initial position to the dispensing position.
- 23. A cartridge reload comprising a medicament container, wherein said
   cartridge reload is reversibly receivable by the reloadable medicament dispenser of claim 22.
  - 24. Kit of parts comprising the reloadable medicament dispenser of claim 22 and the cartridge reload of claim 23.

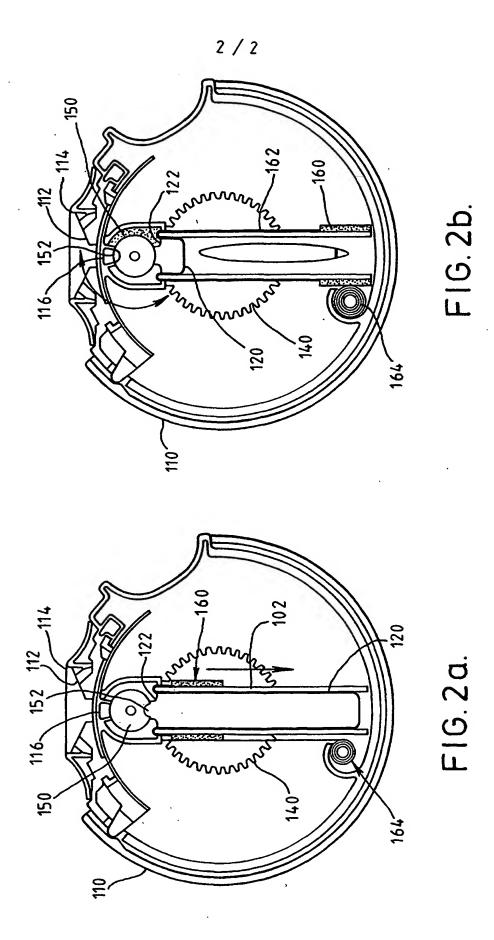
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- 25. A medicament dispenser according to any of claims 1 to 22, wherein the medicament container is charged with medicament.
  - 26. A medicament dispenser according to claim 25, wherein the medicament is in a form selected from the group consisting of dry powder, liquid, solution, gaseous, suspension, tablet, capsule and nebule.
- 27. A medicament dispenser according to claim 26 additionally wherein the medicament is in dry powder form.

- 28. A medicament dispenser according to any of claims 25 to 27, wherein the medicament is suitable for the treatment of respiratory disorders.
  - 29. A medicament dispenser according to any of claims 25 to 28, wherein the medicament is salmeterol xinafoate.
- 20 30. A medicament dispenser according to any of claims 25 to 28, wherein the medicament is fluticasone propionate.
- 31. A medicament dispenser according to any of claims 25 to 28, wherein the medicament is a combination of salmeterol xinafoate and fluticasone
   propionate.

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# A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61M15/00

According to International Patent Classification (IPC) or to both national classification and IPC

#### **B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols) IPC 7  $\,$  A61M  $\,$ 

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 20589 A (EGGIMANN THOMAS ;JAGO PHARMA AG (CH); KELLER MANFRED (DE)) 12 June 1997 (1997-06-12) abstract the whole document	1-31
(	US 4 678 106 A (NEWELL ROBERT E ET AL) 7 July 1987 (1987-07-07)  abstract; figure 1	1-6, 9-11,13, 15-26, 28-31
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	abstract; figure 5  -/	

X Further documents are listed in the continuation of box C.	Patent family members are listed in annex.
Special categories of cited documents:      A* document defining the general state of the art which is not considered to be of particular relevance      E* earlier document but published on or after the international filling date      L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)      O* document referring to an oral disclosure, use, exhibition or other means      P* document published prior to the international filling date but later than the priority date claimed	<ul> <li>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</li> <li>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</li> <li>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</li> <li>"&amp;" document member of the same patent family</li> </ul>
Date of the actual completion of the international search 25 October 2001	Date of mailing of the International search report  02/11/2001
Name and mailing address of the ISA  European Patent Office, P.B. 5818 Patentiaan 2  NL – 2280 HV Rijswijk  Tel. (+31–70) 340–2040, Tx. 31 651 epo nl,  Fax: (+31–70) 340–3016	Authorized officer  Lakkis, A



Inter 1 Application No
PCT/EP 01/06304

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